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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,540

09/05/2003

Steve Koh

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

12/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/656,540

Applicant(s)

KOH ET AL.

Examiner

CHRISTOPHER A. FLORY

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 33-38 have been considered but are moot in view of the new ground(s) of rejection.

It is noted that the steps of determining a subsequent respiratory cycle length and adjusting the atrial overdrive pacing rate based on the subsequent cycle length is merely a repetition of the first two steps of the claimed process. A mere repetition of steps does not serve to distinguish over the art as such a repetition has been held to be obvious. Further, each of the applied references is considered to clearly show a reiterative process (e.g. King, Figures 5 and 6; Thornander, Figure 4) and disclose continued monitoring of physiological parameters, i.e. the respiratory characteristic. Due to the naturally cyclical but variable nature of respiration and heart beat, it would further be obvious to periodically update the delivery protocol based on the current physiological readings.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 7,155,278, hereinafter King'278) in view of Cho et al. (US 2005/0119711, hereinafter Cho'711).

Regarding claims 33 and 38, King'278 teaches a method and implantable device for cardiac stimulation (Figs. 1, 5-7) comprising delivering one or more pacing pulses to an atrium with a pacing rate that is varied with respect to a time-based intrinsic rate (column 2, lines 47-67; column 3, lines 47-67; column 6, lines 17-31; column 7, lines 15-31); determining a plurality of atrioventricular conduction interval times based on the pacing pulses (column 6, lines 7-31); determining a respiratory characteristic based at least in part on the AVI times (claim 10); and conducting this process in a reiterative or subsequent manner (e.g. Figures 5 and 6).

Further regarding claims 33 and 38, King'278 discloses determining respiratory characteristics such as frequency, depth, pattern, and variability (column 5, lines 53-65), which is considered to reasonably include a determining of the cycle length since cycle length is a simple mathematical relation to frequency. Alternatively in the same field of endeavor, Cho'711 teaches determining cycle duration length in a reiterative manner to verify detection of a valid apnea cycle or disorder breathing episode (paragraphs [14], [15], [52], [54], [55]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and system of King'278 with the determination specifically of respiration cycle length to provide King'278 with the same advantages.

Further regarding claims 33 and 38, King'278 discloses the invention substantially as claimed, but does not expressly disclose that the atrial pacing is an overdrive pacing. In the same field of endeavor, Cho'711 teaches that overdrive pacing to alleviate a disordered breathing condition such as apnea without waking the patient (paragraphs [8], [16], [32]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system and method of King'278 with overdrive pacing as taught by Cho'711 to provide King'278 with the same advantages. Alternatively, overdrive pacing is a common and well known means of pacing within the art.

Regarding claim 34, King'278 discloses detecting the interval pattern indicative of either normal respiration or abnormal respiration (claim 10; column 1, lines 10-30; column 2, lines 5-26; column 6, lines 7-31).

Regarding claims 35-37, King'278 discloses the invention substantially as claimed, but does not expressly disclose that normal respiration be indicated by a substantially cyclical interval pattern, and that abnormal respiration be indicated by absence of a cyclical interval pattern. In the same field of endeavor, Cho'711 teaches that normal breathing is typically indicated by heart rate cycles (i.e. a cyclical interval pattern) of less than 25 seconds, whereas apnea-hyperapnea cycles are represented by heart rate cycles of 40-80 seconds, i.e. an absence of the 25 second cyclic pattern of normal sleep. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by King'278 with the cyclic pattern recognition indicative of normal and abnormal respiration as taught by Cho'711

to provide the King'278 system and method with the same advantage of discriminating between normal and apnea-hyperapnea breathing.

4. Claims 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. (US 4,712,555, hereinafter Thornander'555) in view of Warner et al., "Beat-by-Beat Modulation..." (hereinafter referred to as Warner and Loeb; for full citation, see page 2 of the IDS submitted by Applicant on 5 September 2003), and further in view of Cho'711.

Regarding claims 33 and 38, Thornander'555 discloses a method comprising delivering one or more pacing pulses to an atrium (ABSTRACT; column 2, line 67 through column 3, line 7) at a rate that varies with respect to an intrinsic rate (ABSTRACT; column 2, line 47 through column 3, line 6); determining one or more atrioventricular conduction interval times based on the pacing pulses (ABSTRACT; column 3, lines 37-45); and determining a respiratory characteristic based at least in part on the AV conduction interval times (column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68); and performing this method in a reiterative manner (e.g. Figure 4).

It is noted that increased workload and changes in heart rate as disclosed in Thornander'555 are being understood as respiratory characteristics, because increased workload (i.e. exercise) produces an increased respiratory frequency, while it is known that heart rate is an indicator of respiratory state, since inhalation raises the instantaneous heart rate slightly, while exhalation decreases instantaneous heart rate.

Further regarding claims 33 and 38, Thornander'555 discloses the instant invention substantially as claimed except that the respiratory cycle length is determined based on the atrioventricular conduction interval times. In the same field of endeavor, Warner and Loeb teaches that AV interval shows a 1-to-1 correlation to the respiratory cycle length both with and without pacing (page 1127, col.2, paragraph 4 through page 1128, end of column 2; p. 1131, col. 2, paragraph 1; Fig. 1). It follows that a change or trend in AV conduction interval times would be sufficient to determine a relative respiratory cycle length. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Thornander'555 to determine respiratory cycle length based on a comparison of AVIs as disclosed in Warner and Loeb since it has been shown in Warner and Loeb that a change in respiratory cycle length correlate in a 1-to-1 manner to a specific change in AV conduction interval times and vice versa.

Further regarding claims 33 and 38, Thornander'555 discloses the invention substantially as claimed except that the measured respiratory characteristic specifically be the respiratory cycle length. In the same field of endeavor, Cho'711 teaches determining cycle duration length in a reiterative manner to verify detection of a valid apnea cycle or disorder breathing episode (paragraphs [14], [15], [52], [54], [55]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and system of Thornander'555 with the determination specifically of respiration cycle length to provide Thornander'555 with the same advantages.

Further regarding claims 33 and 38, Thornander'555 discloses the invention substantially as claimed, but does not expressly disclose that the atrial pacing is an overdrive pacing. In the same field of endeavor, Cho'711 teaches that overdrive pacing to alleviate a disordered breathing condition such as apnea without waking the patient (paragraphs [8], [16], [32]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system and method of Thornander'555 with overdrive pacing as taught by Cho'711 to provide Thornander'555 with the same advantages. Alternatively, overdrive pacing is a common and well known means of pacing within the art.

Still further regarding claim 38, Thornander'555 shows an implantable cardiac stimulation system (Fig. 10, pacemaker 16) comprising sensing circuitry operative to sense atrial and ventricular events (P-wave sense/pace amp 48, R-wave sense/pace amp 56); a processor connected to the sensing circuitry (Fig. A-1, microprocessor 408) operative to determine one or more A-V conduction interval times based on the delivered stimulation pulses (ABSTRACT; column 3, lines 37-45) and further operative to determine a respiratory characteristic based at least in part on the A-V interval times (column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68); and further comprising a pulse generator operative to generate stimulation pulses for delivery to a patient's heart (Fig 10, pulse generator logic 42 and pulse output driver circuits 44 connected to heart 18), and at least one electrode (atrial lead 22 with tip electrode 24; ventricle lead 30 with electrode 46).

Regarding claims 34-37, Thomander'555 discloses the invention substantially as claimed, but does not expressly disclose that normal respiration be indicated by a substantially cyclical interval pattern, and that abnormal respiration be indicated by absence of a cyclical interval pattern. In the same field of endeavor, Cho'711 teaches that normal breathing is typically indicated by heart rate cycles (i.e. a cyclical interval pattern) of less than 25 seconds, whereas apnea-hyperapnea cycles are represented by heart rate cycles of 40-80 seconds, i.e. an absence of the 25 second cyclic pattern of normal sleep. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Thomander'555 with the cyclic pattern recognition indicative of normal and abnormal respiration as taught by Cho'711 to provide the King'278 system and method with the same advantage of discriminating between normal and apnea-hyperapnea breathing.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

10 December 2008

/George Manuel/
Primary Examiner